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The Department of Defense Pharmacoeconomic Center

UPDATE

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A Matter of Perspective (Editorial)

Doesn't this sound like the title for a Star Trek episode? Dr. Torkildson addresses the recapture of prescriptions from the retail network and why one shouldn't get hung up on volumes of prescriptions as the best predictor of opportunities to decrease costs.

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Why Pay More?

Choosing a Second Generation Antihistamine

Lt Col Ed Zastawny's task was to write an "excellent, succinct" article about the additional opportunities for cost avoidance in this drug class. Looks like he succeeded.

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DoD P&T Highlights

(or P&T Committee Cliff Notes..)

The DoD Pharmacy & Therapeutics (P&T) Committee and the DoD P&T Executive Council met in San Antonio in February 2002. This article gives a brief overview of the meetings and a summary of changes made to the Basic Core Formulary (BCF) and the National Mail Order Pharmacy (NMOP) Formulary. Key BCF changes:

- **BCF Additions** - azithromycin (Zithromax) 250 mg tablets (does not require Z-pak formulation); clopidogrel (Plavix); conjugated estrogens/medroxyprogesterone oral (Prempro) - does not include Premphase; fluticasone/salmeterol inhaler (Advair); levonorgestrel 0.75 mg (Plan B).
- **Important BCF clarification:** the current BCF listing for brimonidine tartrate ophthalmic solution has been clarified to specify the new Alphagan P 0.15% formulation. The new formulation provides comparable IOP-lowering efficacy and a 41% decrease in allergic conjunctivitis. Plus, the manufacturer is phasing out the older formulation.

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Editors' Letters

No one has sent us any letters yet. We feel unloved... <sniff>

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Last Issue

Coming Up

Angela Allerman, Pharm.D. resurrects the New Drug Watch column

Advair

Will Ease of Use Improve Compliance & Outcomes?

CDR Denise Graham addresses the comparative usage of Advair, Flovent, and Serevent in MTFs and the retail network; reviews provider opinion concerning the potential humanistic impact of this BCF addition; and addresses a specific safety concern regarding the treatment of exacerbations in patients on Advair.

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Barb's Barbs

Generics vs. Brand Names

MAJ Barbara Roach's take on generic drugs. Do **YOU** remember the Generic Scandal of 1989?

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Contract Compliance

DoD Mandatory Source Contracts for Generics

LCDR Ted Briski provides a brief explanation of how the contracting process works (more next month!) and asks the question: why don't more facilities comply with mandatory source generic contracts? (Hint: the answer is not: "who cares"?)

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PDTS Corner

Update on the Pharmacy Data Transaction Service

On-line Patient Profiling in CHCS

On-line Patient Profiling is Here! Sonya Edom, PDTS Customer Service Support Center (CSSC) Help Desk Manager, explains On-line Patient Profiling, a new CHCS option allowing providers or pharmacy personnel to view the entire patient profile (combined CHCS and PDTS data) for patients registered in their CHCS system. On-line Patient Profiling allows viewing of all prescriptions filled at any of the three MHS points of service (MTFs, NMOP, retail network pharmacies). [Editors' Note: this is deeply cool!]

PDTS Standard Reports

The last PEC Update gave a brief introduction to the new PDTS Report Request Form and listed the standard reports currently available. In this issue, COL (Ret) Roger Williams, PDTS CSSC Clinical Support Supervisor, provides a more in-depth discussion of standard reports and how to order them.

Data Integrity

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We need it! Hector Morales, PDTS CSSC Day Shift Supervisor, talks about data integrity, an essential element in ensuring that accurate and beneficial clinical information is provided to providers and pharmacy personnel. On a daily basis, PDTS receives numerous prescription transactions with inaccurate days

Excellent Quote of the Month

"The brand names of today don't immediately become useless when their patents run out."

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Signing up for the Update

Would you like to receive the e-mail newsletter direct to your Inbox? Let us know by e-mailing Carol Scott, the PEC secretary, at carol.scott@amedd.army.mil.

Submitting Items for the Update

Do you have an article you'd like to see published in the PEC Update? Just send CAPT Torkildson or Shana Trice an e-mail, or call the PEC at DSN 421-1271, Commercial (210) 295-1271.

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supply, metric quantities, or both. Breaking the "garbage in - garbage out" cycle begins with **YOU**!

Top 50 Drugs for Jan & Feb 2002 by Point of Service

Preston Hardy, PDTS CSSC, Clinical Support Coordinator, updates us on the top 50 drugs in Military Treatment Facilities (MTFs), the NMOP, and the retail network for January & February.

PDTS TIP for CHCS USERS

When the CSSC calls and gives an MTF pharmacy the PDTS Rx number, pharmacy users can go through the menu path **OPM>PM>PPQ** and enter in the PDTS Rx number to view the prescription.

Unrelated Links

Department of Health & Human Services National Women's Health Information Center
Info on a wide array of women's health topics, including emergency contraception

DSCP DMM-Online: Vaccine Update
Check availability and contracting information on pharmaceutical vaccines, including the most recent info on Hepatitis A vaccine

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EDITORIAL

A Matter of Perspective

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CAPT Joe Torkildson, MC, USN
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Editors' Letters

Please send us some.

Please send your letters to the editors to CAPT Joe Torkildson at Joseph.Torkildson@amedd.army.mil *or Shana Trice at* Shana.Trice@amedd.army.mil

There have been some unique challenges presented during the last six months to persons involved in the administration of the DoD pharmacy benefit, on both the national and local levels. In my 20 years as a military prescriber, this is the first time I can remember that hospital commanders, pharmacy chiefs, and other interested stakeholders have been concerned half way through the fiscal year that they might in fact not be able to fully execute their pharmacy budgets.

A variety of events have contributed to the situation – a 15% plus-up in the pharmacy budget, Aciphex, and generic fluoxetine, to name just a few. Admittedly, it's a situation many of us would have liked to experience more often in the past. And it's encouraging to see so many individuals looking at this situation in the manner that it was intended, as an opportunity to decrease the overall cost of the pharmacy benefit by bringing a greater number of prescriptions into the MTFs where they can be filled at a lower cost to the government than in the retail network.

Unfortunately, this change has put many folks in the middle of very unfamiliar territory. Smart people who have spent their entire careers trying to figure out how to spend less money are now trying to figure out how to spend more. Logically, they have referred to data now available from the PDTS Customer Service Support Center concerning the top drugs being filled in the retail network in order to find likely candidates for recapture. As a result, we have been hearing a growing number of complaints regarding the limitation imposed by the statin contract on the inability of MTFs to add atorvastatin to their formularies and recapture atorvastatin prescriptions. This appears to be logically based on the fact that the number two item on the list, when sorted by prescription volume, is 10 mg atorvastatin.

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I submit, however, that in this case "logical" is not the same thing as "correct." I base this assertion on a point made several times by my managerial economics teacher, that the goal of successful businesses is not to maximize volume but to maximize profit. To that end, we need to look at the list of top drugs in the retail network ranked not by volume, but by overall cost to the government [(ingredient cost + dispensing fee) – copay]. If we look at the top 11 drugs on that list, we see a different set of priorities.

- The number 1 drug/dose combination is omeprazole 20 mg. Remember that for 50% of this time period we had a closed class contract for omeprazole and it was a BCF item, yet we filled over 104,000 prescriptions for omeprazole in the retail network, at a cost to the government of over $14.7M. Did your MTF take omeprazole off your local formulary in October because you can get rabeprazole for 1/10 the cost? If so, know that in return the government is effectively paying $4.00/tablet ($141 per prescription/36 tab average per prescription) for any omeprazole you "cost shifted" to the network.

- Number 3 on the list is lansoprazole 30 mg. Did you put lansoprazole on your local formulary to take advantage of the $0.99/tablet cost and hopefully entice some providers to switch from omeprazole who were reluctant to use rabeprazole, or did you decide that the difference between $0.22/tablet and $0.99/tablet was too high for you to take the risk? Consider that decision in light of the fact that the average 34-day lansoprazole prescription in the network costs the government on average $127, or $3.74/tablet.

- Number 5 on the list is simvastatin 20 mg! There were almost 55,000 prescriptions filled in the retail network for this closed-class contract, BCF drug during the 6-month time period from July 2001 to December 2001, for a total cost to the government of over $7M. Atorvastatin doesn't show up until #6, with 117,000 prescriptions filled at a cost of $6.9M for the 10-mg strength. If you do the math some interesting facts become apparent:

    - The contract price for simvastatin 20 mg is $0.59/tablet, while the retail cost to the government is $3.30/tablet.

    - The FSS price for atorvastatin 10 mg is $0.69/tablet, while the retail cost to the government is $1.50/tablet.

    - Based on this, for every tablet of 20 mg simvastatin we bring back into the MTF, the government saves $2.71 and we adhere to the contract.

    - Conversely, for every tablet of 10 mg atorvastatin we bring back into the MTF we save only $0.81, and we place the contract at risk.

Therefore, we stand to recapture a lot more money by aggressively targeting the simvastatin prescriptions being filled in the network than by violating the contract in an attempt to bring atorvastatin prescriptions back in. The return on the latter maneuver is marginal, and we run the risk of losing the tremendous price break we presently enjoy for simvastatin. This is great news for those who are workload-conscious; you get a much larger return on your workload dollar by recapturing simvastatin prescriptions than you do atorvastatin prescriptions.

By the way, to round out the top 11 we have the COX-2s, which many facilities have decided

not to make available on formulary; cetirizine, zolpidem, azithromycin, tramadol, and propoxyphene/acetaminophen, which are not restricted from being on MTF formularies; and albuterol and conjugated estrogens, both of which are already on the BCF.

So what's the point of all this? There will always be prescriptions filled in the retail network. There are drugs where it makes tremendous sense to recapture prescriptions because of the tremendous difference in the cost to the government between venues. There are others, like atorvastatin, that raise a lot of interest and which people presume make sense to recapture, but actually don't when one critically analyzes the potential benefit vs. the potential risk. I think we need to be careful in those situations that we are truly analyzing the situation dispassionately, rather than letting pressure from patients and providers affect the way we look at the situation.

The reality is, simvastatin is an great drug. It has an excellent safety record over a substantially longer period of time than atorvastatin, an excellent efficacy profile based both on clinical trial data and DoD's own usage data, and a proven benefit in reducing CAD-related mortality and morbidity that is not shared by its closest competitor. Yet atorvastatin is clearly the market leader in the civilian community.

Our opinion is that this is due to marketing, not value. Based on the comprehensive analysis I have outlined, we feel we have avoided a significant amount of cost with the statin contract, not just for MTFs but also for the enterprise as a whole. If we could get half of the simvastatin prescriptions currently being filled in the network back into the MTF, we could avoid another $2.8M in cost. If we could convince 25% of prescribers in the network to prescribe simvastatin instead of atorvastatin and filled those prescriptions in the MTF, we could save an additional $1.0M. And if the lessons learned regarding why patients go out to the network to fill simvastatin prescriptions are applied to the other BCF drugs on the top 25 or top 50 list, our cost avoidance will be even greater.

It really comes down to a matter of perspective.

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Why Pay More?

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Choosing a Second Generation Antihistamine

LtCol Ed Zastawny, USAF, BSC
Air Force Pharmacy Officer, DoD Pharmacoeconomic Center

Background

In May of 2000, DoD awarded the joint DoD/VA non-sedating antihistamine (NSA) contract to Aventis for fexofenadine (Allegra®). The contract directs that NSA-naïve patients ("new starts") who require a non-sedating antihistamine and who are receiving prescriptions from providers at DoD military treatment facilities (MTFs) be started on fexofenadine. Loratadine (Claritin®) oral tablets, Reditabs®) and desloratadine (Clarinex®) are excluded from MTF formularies. The contract does not mandate that patients currently stabilized on another non-sedating antihistamine be switched to fexofenadine, but MTFs may decide locally to encourage their providers to switch patients.

The contract does not affect the formulary status of non-sedating antihistamines at the National Mail Order Pharmacy (NMOP) or in the retail network. Desloratadine (Clarinex) was recently added to the NMOP Formulary.

While cetirizine (Zyrtec®) belongs to the second generation antihistamine group along with fexofenadine, loratadine, and desloratadine, it is not technically considered a non-sedating antihistamine, and was not included in the DoD/VA contract solicitation. Therefore, cetirizine was not affected by the contract award. MTFs may have cetirizine on their local formularies if they choose to do so.

Comparison of Second Generation Agents

Safety/Tolerability

- Fexofenadine and cetirizine have similar adverse effect profiles, except for sedation.
- Cetirizine has twice the sedation potential of fexofenadine (6% vs. 3%, respectively). The incidence of sedation or drowsiness with fexofenadine doesn't differ from that of placebo (3%).
- The risk of QTc prolongation with both medications (unlike terfenadine and astemizole) is extremely low.

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Efficacy/Effectiveness

- Fexofenadine is FDA-approved for the treatment of seasonal allergic rhinitis (SAR) and chronic idiopathic urticaria (CIU). Loratadine and cetirizine share these FDA indications.
- Several studies show similar or equivalent efficacy of fexofenadine compared to cetirizine in the treatment of SAR and CIU.

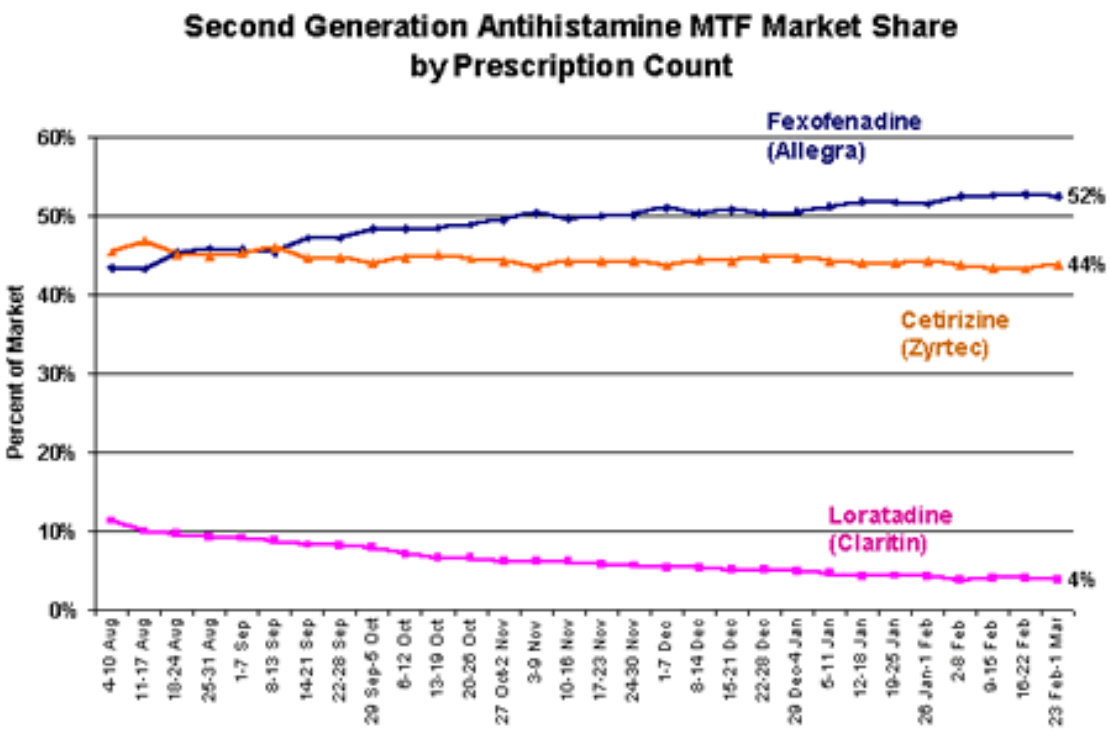
Price/Cost

The contract provides DoD a significant price reduction for fexofenadine, making it the most cost-effective choice for patients requiring therapy with a second generation antihistamine. The following table outlines the current prices of these agents.

Drug	Cost/unit	Cost/day
Fexofenadine (Allegra ®)180 mg	$ 0.60/unit	$ 0.60/day
Cetirizine (Zyrtec ®)10 mg	$ 0.89/unit	$ 0.89/day
Desloratadine (Clarinex ®) 5 mg*	$ 0.89/unit	$ 0.89/day
Loratadine (Claritin ®) 10 mg	$ 1.28/unit	$ 1.28/day
* with FSS voluntary price reduction from Schering		

Other Factors

The following chart details the usage trends of NSAs in the MTFs from PDTS data. MTF providers and pharmacists have done a great job of increasing fexofenadine's MTF market share, and there is no evidence that prescriptions for the other NSAs are being shifted to the NMOP or the retail network. This suggests that patients being seen at the MTFs who have a clinical need for one of the non-contracted NSAs are able to fill their prescriptions at the MTFs.



For MTF-specific usage/dispensing patterns, your own CHCS report function (^**ODU**) can help. For additional information on usage patterns outside your MTF (i.e., NMOP and retail network), the Pharmacy Data Transaction Service (PDTS) Customer Service Support Center (CSSC) may be able to help. A PDTS report request form can be found on the PEC website at : http://www.pec.ha.osd.mil/PDTS/PDTS_web/PDTS_Report_Request_Form.doc. This form is **required** for all reports requested from the PDTS database. Once this report form is completed it should be e-mailed to LTC Don Degroff at donald.degroff@amedd.army.mil. When completing the form, please be as specific as possible. For additional help in formulating your report request and completing the form, contact the CSSC at 1-866-ASK4PEC (866-275-4732).

Fexofenadine is "waiverable" in aircrew members from all three services. Cetirizine, because of its higher incidence of drowsiness, is not waiverable in aircrew members of **ANY** service. Service specific guidance regarding the use of medications in aircrew members can be obtained at the following websites:

- Army: http://books.army.mil/cgi-bin/bookmgr/BOOKS/R40_8/CCONTENTS
- Navy: http://www.nomi.med.navy.mil/Nami/WaiverGuideTopics/medications.htm
- Air Force: http://afpubs.hq.af.mil/pubfiles/af/48/afi48-123/afi48-123.pdf , attachment 7, page 162-164.

Due to a recent contract modification, fexofenadine 60- and 180-mg tablets are now available in 500 count bottles at the same contract prices ($0.37 and $ 0.60, respectively). The 60-mg capsules are no longer part of the contract. This should allow easier stocking and filling of Baker cells.

The Bottom Line

While the NSA contract has greatly decreased the cost of effectively treating SAR, it is apparent from the above chart that most of fexofenadine's increased market share has resulted from a net movement of patients from loratadine to fexofenadine, with cetirizine's market share remaining fairly stable. It is also apparent from the above table that fexofenadine offers a $0.29/patient/day price advantage over cetirizine. So the question arises - Why not try an equally effective, **NON**-sedating, lower cost (30% less) option first? Fexofenadine is a safe, effective, well-studied, **NON**-sedating antihistamine. It's FDA indicated for seasonal allergic rhinitis and chronic idiopathic urticaria. It's 30% less expensive per dose than cetirizine or desloratadine, and more than 50% less expensive per dose than loratadine. For NSA-naïve patients (and others): **WHY PAY MORE?** Start them on fexofenadine.

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DoD P&T Committee Meeting Highlights

News from the 12 and 13 Feb 2002 meetings of the DoD P&T Executive Council and the DoD P&T Committee

Shana Trice, Clinical Pharmacy Specialist
DoD Pharmacoeconomic Center

Complete minutes of the DoD Pharmacy & Therapeutics (P&T) Committee and the DoD P&T Executive Council meetings are available on the PEC website at www.pec.ha.osd.mil/PT_Committee.htm. The next meetings have been rescheduled since the minutes of the last meeting were published. They will now be held 7 and 8 May 2002 (rather than 8 and 9 May), at Fort Sam Houston, Texas.

Quick Links

DoD P&T Executive Council Meeting (12 February 2002)

- Angiotensin receptor blockers (ARBs)
- Carbamazepine
- Cyclooxygenase-2 Selective NSAIDs (COX-2 Inhibitors)
- Flouroquinolones
- Leutinizing hormone releasing hormone (LHRH) agonists
- Once-daily methylphenidate for ADHD: Follow-up on BCF addition of Concerta
- Nasal corticosteroid inhalers
- Non-sedating antihistamine contract & formulary status of desloratadine (Clarinex); Second generation antihistamines
- Proton pump inhibitors
- Statins
- Triptans

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- BCF additions, changes & clarifications:

  BCF Additions: azithromycin (Zithromax) 250 mg, clopidogrel (Plavix), conjugated estrogens/medroxyprogesterone (Prempro), fluticasone/salmeterol inhaler (Advair), levonorgestrel 0.75 mg oral (Plan B)

  Considered for BCF addition, but not added: gabapentin

  Tabled until May 2002:Potential addition of Effexor XR to the BCF; clarification of BCF listing for phenytoin

- Potential impact of new generics (fluoxetine, metformin)
- Getting input from providers about P&T Issues
- Contract compliance
- Contract awards, renewals, and terminations

DoD P&T Committee Meeting (13 February 2002)

Status of Lovastatin in the NMOP
Newly Approved Drugs
Prior Authorization Changes
Controlled distribution program for peginterferon alfa 2b (PEG-Intron)

Combined List: Changes to the Basic Core Formulary and National Mail Order Pharmacy (NMOP) Formulary

DoD P&T Executive Council Meeting (12 February 2002)

Potential contracting initiative for angiotensin receptor blockers (ARBs) and/or addition of an ARB to the BCF: clinical review in progress - The Council is scheduled to consider clinical information, usage data, provider opinion, and other information at the May 2002 meeting to assess the need for addition of an ARB to the BCF and the therapeutic interchangeability of the ARBs for a potential contracting initiative.

Joint VA/DoD contracting initiative for carbamazepine - The Council voted to

support a joint VA/DoD solicitation for a single source of generic carbamazepine that allows MTFs to use either the contracted generic carbamazepine or brand name Tegretol (assuming that Tegretol does not in fact win the contract). Considerations included current usage in MTFs (85% of purchases are for branded Tegretol); provider opinion (most respondents were not concerned about whether the drug provided at their facility was generic or brand name, but wanted a single product/manufacturer selected to avoid changes in tablet color, shape, etc.); increasing use of carbamazepine for neuropathic pain, where bioequivalence is a lesser concern than for seizure control; the provisions of the proposed contract; and the value of participating with the VA in the contracting action. (Please see the DoD P&T Council minutes for a more extensive discussion.)

COX-2 Inhibitors - The Council asked DSCP to issue a request for Blanket Purchase Agreement (BPA) price quotes to the manufacturers of celecoxib, rofecoxib, and valdecoxib for the purpose of adding a COX-2 inhibitor to the BCF. The considerations that went into this request included:

- Usage of COX-2 inhibitors across the three MHS points of service
- The percentage of MTFs that already have one or more COX-2 inhibitors on formulary
- A model that estimates the total cost to DoD of adding a COX-2 inhibitor to the BCF given assumptions about the percentage of switches from non-selective NSAIDs to COX-2 inhibitors, the absolute increase in COX-2 inhibitor prescriptions among patients not previously receiving an NSAID, the movement of COX-2 prescriptions from the retail networks to MTFs, and the anticipated percent decrease in average cost per unit for COX-2 inhibitors at MTFs and the NMOP that would result from selecting one COX-2 inhibitor for the BCF
- The recent increase in funding for MTF pharmacies, with the purpose of making more drugs available at MTF pharmacies so that beneficiaries are not forced to go to a more expensive point of service (e.g. the retail network) to obtain their medications
- Anticipated reductions in MTF expenditures in some major drug classes due to lower prices for some medications (e.g., rabeprazole) and anticipated price reductions associated with the availability of new generic medications (e.g., fluoxetine, metformin)
- The likely availability of similar agents in the future, increasing price competition in the class

The Council plans to consider the price quotes, as well as the relative safety, tolerability, efficacy/effectiveness, and other relevant factors pertinent to each drug, in selecting a COX-2 inhibitor for the BCF. The Council reserves the right to not select a COX-2 inhibitor for the BCF if it is determined to be not in the best interest of the government. The Council has previously determined that celecoxib and rofecoxib are insufficiently therapeutically interchangeable for a closed class contract, so the COX-2 drug class would remain “open” on

the BCF. The request for BPA price quotes also asks the pharmaceutical companies to submit their plans for assisting MTFs in targeting the use of COX-2 inhibitors to the patients at greatest risk for gastrointestinal events. The Council encourages the continued use of COX-2 guidelines at MTFs in the efforts to ensure appropriate, cost-effective use of COX-2 inhibitors.

Joint VA/DoD contracting initiative for a "workhorse" fluoroquinolone still possible - The Council concluded in Nov 01 that levofloxacin (currently on the BCF) and gatifloxacin are therapeutically interchangeable and that either agent would be clinically acceptable as the “workhorse” oral fluoroquinolone. The Council agreed that a BPA offered by Ortho-McNeil to both DoD and the VA that removes the market share requirements and gives a uniform price of $2.00/tab system-wide would reduce overall expenditures while avoiding the potential need to switch products. However, because the the Council also believes that it is still clinically acceptable to participate in a joint DoD/VA contract, the Council will support whatever joint action the VA/DoD contracting workgroup decides on.

Contracting initiative for Leutinizing Hormone Releasing Hormone (LHRH) agonists still pending; triptorelin not considered to be therapeutically interchangeable with goserelin and leuprolide - The joint VA/DoD solicitation to select an LHRH agonist (for the treatment of prostate cancer only) has not yet been released. AstraZeneca and TAP have indicated that the DoD Blanket Purchase Agreements (BPAs) for goserelin (Zoladex) and leuprolide (Lupron) will remain in place until the new contract is awarded. The Council agreed that triptorelin (Trelstar), a new LHRH agonist for the treatment of prostate cancer, should not be considered therapeutically equivalent to leuprolide and goserelin at this time due to the relatively small amount of clinical trial data available and concern over the drugs ability to continue to suppress testosterone production with repeated dosing, and therefore should not be added to the LHRH agonist solicitation. [Triptorelin 1- and 3-month depot formulations (Trelstar, Trelstar LA) were added to the NMOP Formulary, which already includes Zoladex and Lupron, at the DoD P&T Committee meeting the following day.]

Analysis of midday dosing with methylphenidate sustained/extended-release formulations; is Concerta reducing the number of ADHD patients who require midday (school) doses of ADHD meds? - The answer appears to be yes. Based on random samples of methylphenidate-SR prescriptions filled between Oct 99 and Sep 00 and Concerta prescriptions filled between Oct 00 and Dec 01, a total of 78/193 patients (40%) with prescriptions for methylphenidate-SR required midday dosing, compared to 17/195 patients (8%) with prescriptions for Concerta. The analyses indicate that the addition of Concerta to the BCF in November 2000 improved a humanistic outcome of drug therapy by decreasing the frequency of midday dosing of methylphenidate products for ADHD patients.

Nasal corticosteroid inhalers; once-daily aqueous nasal corticosteroid needed for the BCF - The Council agreed that DoD could participate in a joint VA/DoD solicitation that could result in the addition of flunisolide or budesonide to the BCF, but neither of these drugs can be the sole nasal corticosteroid on the BCF. Fluticasone (Flonase) is currently on the BCF.

Report on the non-sedating antihistamine contract; desloratadine (Clarinex)

excluded from the BCF, added to the NMOP Formulary - Changes to the non-sedating antihistamine (NSA) contract include addition of the 500-count bottles of fexofenadine 60- and 180-mg tablets to the contract and the removal of 60-mg capsules from the contract, effective 28 Feb 2002. The capsule formulation is being phased out. The contract prices for the 60-mg and 180-mg tablets remain unchanged at $0.37 and $0.60 per tablet, respectively.

The FDA recently approved desloratadine (Clarinex). Under the terms of the NSA contract, desloratadine cannot be added to the BCF or MTF formularies while the contract is in effect. [The NSA contract does not apply to the NMOP. Desloratadine was added to the NMOP Formulary, which already includes loratadine, at the DoD P&T Committee the following week.]

Second-generation antihistamines: cetirizine (Zyrtec) vs. fexofenadine (Allegra) - Cetirizine (Zyrtec) 10 mg is priced at $0.89 per day, compared to only $0.60 per day for fexofenadine 180 mg. MTFs fill almost as many prescriptions for cetirizine as for fexofenadine. The Council agreed that many patients currently treated with cetirizine could be effectively treated with fexofenadine, especially patients who are newly being started on a second generation antihistamines. The Council agreed that the PEC should publish an article in the PEC Update to encourage greater utilization of fexofenadine—which appears in this issue! See LtCol Ed Zastawny's article on Page 3.

Proton pump inhibitors; conversion from omeprazole to rabeprazole - Rabeprazole (Aciphex) replaced omeprazole (Prilosec) on the BCF on 1 Oct 01. The Council reviewed provider input concerning specific problems with dosing, tolerance or patient response to rabeprazole vs. omeprazole. Providers were also asked if the switch was problematic for providers, patients or pharmacists. The PEC received 41 provider responses from 32 MTFs. Most reported no problems and were pleased with the decrease in cost. Favorable comments included the perception of a higher success rate with rabeprazole and preference for the smaller size of the tablet compared to omeprazole capsules. A few providers reported a higher rate of treatment failures with rabeprazole, with one provider expressing concern about the procedure used by the MTF to convert patients.

Statins - The contract for simvastatin (Zocor) has been renewed for its final option year (until 19 Feb 03). For more information, please see the minutes or Dave Bretzke's article "Treating to Goal: Statin Usage in DoD" in the last issue of the PEC Update.

Potential contracting initiative for triptans - After reviewing information from clinical studies and provider input regarding triptans, the Council agreed that patients' clinical needs would not be satisfied if a contract prohibited MTFs from having more than one triptan on their formularies. The Council voted to support any contracting initiative or other pricing agreement that either allows or requires MTFs to have at least two triptans on their formularies.

Potential Impact of New Generics

-

Fluoxetine - Barr Pharmaceuticals' 6-month period of exclusivity for generic fluoxetine expired in late January. On January 29 the FDA approved several additional generic fluoxetine products. At least two companies receiving approval have established FSS pricing for their generic products, at prices of about $0.05 per 10- or 20-mg capsule. If MTFs transition quickly to these significantly less expensive generic products, it is anticipated that the MHS could reduce expenditures for fluoxetine by as much as $13 million over the next year.

- **Metformin -** The FDA approved generic formulations of metformin (Glucophage) on 25 Jan 01. At least six generic companies will market metformin, and five of them have approval for all three strengths (500-, 850-, and 1000 mg). The extended release metformin preparation (Glucophage XR) and combination product with glyburide (Glucovance) are still under patent.

  As of April 2002, FSS prices for generic metformin compared to brand-name Glucophage ranged from $0.11-$0.13 (generic) vs. $0.32 (brand) for the 500 mg tablet; $0.13-$0.22 vs. $0.55 for the 850 mg tab; and $0.14-$0.22 vs. $0.58 for the 1000 mg tablet. This represents an approximate 37.5% reduction in cost for the 500-mg tablet, the most commonly used strength in MTFs. The potential cost avoidance from a 100% conversion from brand to generic metformin (for the 500-mg tablet alone) would be $9.6 million/year.

Obtaining input from MTF providers - Current methods include:

- E-mail groups (effective, but do not reach all MTFs)
- Monthly teleconferences held by the PEC with lead agent medical directors and lead agent pharmacists, with the goal of tapping into already existing communication networks
- Close contact with service-specific chains of command via the chief pharmacy consultants and chief clinical consultants to each Surgeon General
- The PEC is exploring options for creating a chat room/bulletin board section of the PEC web site to facilitate consistent and timely communication.

Compliance with mandatory source generic contracts - The Council views unavailability of contracted products as a patient compliance/safety issue since it may cause patients to receive different looking tablets or capsules each time they receive a prescription. A review of generic contract compliance revealed many instances where MTFs purchased non-contracted products. A small sampling of MTF pharmacy directors indicated that unavailability of the contracted product from the prime-vendor caused MTFs to purchase non-contracted products. PEC and DSCP representatives are scheduled to report back to the Council at the next meeting. For more information, see LCDR Ted Briski's article on Page 7 in this issue of the *PEC Update*.

BCF additions, changes & clarifications

Additions

Azithromycin (Zithromax) 250 mg tablets – This addition was made primarily because of widespread usage in the retail network and almost universal (94%) representation on MTF formularies. The listing does not require that MTFs add the Z-pak dosing form to their formularies, although they are free to do so if they so desire.

Conjugated estrogens/medroxyprogesterone acetate (Prempro) – The Council added all strengths of Prempro to the BCF; the listing does not include Premphase. Prempro was considered for addition based on widespread use in the retail network, formulary status at a majority of MTFs (59%) and because most providers think that the potential for improved compliance may increase effectiveness. Of 141 responses to a provider survey regarding potential addition of Prempro to the BCF, 108 were in favor, 17 opposed, 16 indecisive.

Prempro is more costly than equivalent doses of conjugated estrogens and medroxyprogesterone if the comparison is based on the lowest priced generic equivalent of medroxyprogesterone. However, the fact that many MTFs purchase brand name Provera rather than generic medroxyprogesterone means that the the actual average daily cost (based on prime vendor data) of Prempro is less than the same dosages of medroxyprogesterone and conjugated estrogens via separate tablets ($0.32 vs. $0.39).

Clopidogrel (Plavix) - After clarifying information about bleeding rates with clopidogrel + aspirin in the recent CURE (Clopidogrel in Unstable Angina to Prevent Recurrent Events) trial, the Council added clopidogrel (Plavix) to the BCF.

Fluticasone/salmeterol inhaler (Advair) – After extensive discussion, the Council added all strengths of this combination product to the BCF. The product was considered in response to a request from an MTF provider. For more information, please see the minutes and CDR Denise Graham's article on Advair on Page 5 of this issue of the *PEC Update*.

Levonorgestrel 0.75 mg oral (Plan B) – The Council voted to add the emergency contraceptive product Plan B to the BCF, a decision that is now official. The original vote was contingent upon verification from TMA that the action is consistent with existing DoD policy, which has now been obtained. Information considered by the Council regarding emergency contraceptives in general and Plan B in particular included:

- The original request from an MTF provider

The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Family Physicians (AAFP) recommend and endorse the use of emergency contraception. ACOG estimates that use of emergency contraceptives could prevent as many as half of the approximately 3 million unintended pregnancies that occur each year in the United States, including as many as 700,000 pregnancies that are terminated by abortion.

- The OB/GYN consultants for the three services support the addition of Plan B to the BCF. Emergency contraception counseling should be provided during every annual health maintenance examination per BUMED NOTE 6320 (26 Oct 99) and Article 15-76 of the Manual of the Medical Department, Section VI; Family Planning, Contraceptive Counseling, and Sexually Transmitted Disease Prevention Counseling.
- Ethics consultants for the three services concluded that there are no apparent reasons to preclude the use of Plan B at MTFs, since it is an FDA-approved contraceptive and not, as some argue, an abortifacient. Service regulations and TRICARE policy do not prohibit the coverage of emergency contraceptives. The presence of Plan B on the BCF would not "force" providers to prescribe Plan B. As with all other drugs on the BCF, the decision to prescribe Plan B would be left to the discretion of the individual provider.
- MTFs already provide emergency contraceptive therapy. Most MTFs use regular oral contraceptives in an "off label" fashion, while some MTFs use Plan B.
- Plan B has been shown to be both more efficacious in preventing pregnancy and less likely to cause nausea and vomiting than the commonly used Yuzpe regimen (ethinyl estradiol 100 mcg and levonorgestrel 0.5 mg taken twice, twelve hours apart). The only other approved emergency contraceptive product, Preven, is similar to the Yuzpe regimen, while the use of norethindrone tablets to provide a progestin-only regimen requires the patient to ingest 20 tablets compared to 2 tablets for Plan B.
- Plan B is more costly than other alternatives [$11.63 vs. $3.61 for Preven, $9.92 for the Yuzpe regimen, $9.20 for progestin-only tablets (norethindrone)].
- The need for timely administration of emergency contraception (within 72 hours of unprotected sex, preferably during the first 24 hours, followed by a second dose 12 hours later) supports the argument that the emergency contraceptive should be on the MTF formulary in order to preclude delays that might occur if the medication had to be obtained through a non-formulary or special order request.

- The majority of MTF providers and pharmacists responding to a survey regarding the proposal to add Plan B to the BCF supported its addition (38 in favor, 15 opposed, 14 did not clearly express their position).

Considered for the BCF, but not added

Gabapentin (Neurontin) – Gabapentin was evaluated for potential addition to the BCF based on its high usage in the retail network, its overall cost, and its usefulness in the treatment of neuropathic pain. However, Council members were concerned that gabapentin is not FDA-approved for pain control and that it may pose a large cost burden to small MTFs. They were also concerned that there is very little solid literature to back its use for pain control. The company has a supplemental new drug application pending for FDA approval for treatment of neuropathic pain. The Council decided not to add gabapentin to the BCF.

Tabled until May 2002

- Potential BCF addition of venlafaxine extended release (Effexor XR)
- Clarification of the phenytoin listing on the BCF to include or exclude the new 200- and 300- mg tablets (Phenytek)

Continue to Monitor

- **Availability and pricing of Ortho Novum 7/7/7 -** Ortho Novum 7/7/7 is listed on the BCF. Clinic packs of Ortho Novum 7/7/7 have been available for purchase by MTFs through the Depot or directly from Ortho-McNeil for approximately $7.70/cycle, a price which is not available to MTFs via Prime Vendor because clinic packs are not sold through Prime Vendor. (Commercial packs cost approximately $16.00/cycle). Ortho-McNeil does not plan to renew the Depot contract, which expires at the end of February 2002; Ortho Novum 7/7/7 will no longer be available from the Depot when existing supplies are exhausted. There has been no determination on the long-term availability of the “clinic” packs directly from the manufacturer. The PEC will continue to monitor the situation.

Contract awards, renewals, and terminations

- **Renewed:** diltiazem XR (Tiazac), acetaminophen tablets, levobunolol ophthalmic solution, timolol ophthalmic solution,

clotrimazole cream, and simvastatin (Zocor)

- **Cancelled:** gemfibrozil
- **New contracts awarded:** cyclobenzaprine tablets, isosorbide dinitrate tablets, loperamide capsules, methocarbamol tablets, metoprolol tablets, verapamil immediate release tablets, and lactulose syrup, nitroglycerin patch, and glyburide micronized tablets
- See DSCP's DMM-Online website for a complete list of DoD and DoD/VA contracts.

DoD P&T Committee Meeting (13 February 2002)

Generic lovastatin in the NMOP – The Committee discussed the impact of the recent approval of a generic formulation of lovastatin on the current statin contract and the potential for creating patient dissatisfaction regarding the current structure of copays. The situation has been created in which a patient might submit a prescription for lovastatin to the NMOP in order to obtain the $3.00 generic copay, only to be told that they must use the contracted drug simvastatin and pay a $9.00 copay, unless there is a medical necessity for the use of a noncontracted statin. Unfortunately, reducing the co-pay for simvastatin to the generic copay in this particular situation is not within the purview of the Committee, since simvastatin did not compete directly against generic products when the contract was initially awarded.

Newly approved drugs – The Committee determined the NMOP formulary status and NMOP or retail network formulary restrictions (quantity limits or prior authorization) for 13 new drugs. See the Combined List of Changes to the Basic Core Formulary and the NMOP Formulary for details. Of special note:

- The current BCF listing for brimonidine tartrate ophthalmic solution was clarified to identify the new Alphagan P 0.15% formulation as the specific agent included on the BCF. The new formulation provides comparable IOP-lowering efficacy to Alphagan 0.2% (potentially due to increased bioavailability of the purite formulation as demonstrated in animal studies), but the incidence of allergic conjunctivitis was 41% less with Alphagan P 0.15% than Alphagan 0.2%. The manufacturer plans on phasing out the older formulation.
- Desloratadine (Clarinex) and valdecoxib (Bextra) were added to the NMOP Formulary.
- Anakinra injection (Kineret), triptorelin pamoate depot injection (Trelstar, Trelstar LA)and fondaparinux injection (Arixtra) were added to the NMOP Covered Injectables List. Kineret is subject to prior authorization criteria and a quantity limit.
-

Dexmethylphenidate tablets (Focalin) were specifically excluded from the BCF listing for methylphenidate.

- Bosentan tablets (Tracleer) and lovastatin/niacin (Advicor) were excluded from the NMOP Formulary. Bosentan's closed distribution system makes it impossible to dispense this drug from the NMOP, while Advicor was excluded due to the terms of the statin contract. Advicor will be available from the NMOP only in cases of documented medical necessity.

Prior authorization changes

COX-2 inhibitors – The Committee addressed two issues: 1) a new FDA-approved indication for celecoxib (Celebrex) for acute pain in adults and treatment of primary dysmenorrhea; and 2) the availability of a new COX-2 inhibitor, valdecoxib (Bextra), approved in Nov 2001 for treatment of osteoarthritis, adult rheumatoid arthritis, and primary dysmenorrhea. The existing NMOP PA criteria for COX-2 inhibitors allow use of rofecoxib but not celecoxib for 20 days or less in patients with risk factors for GI adverse events, since celecoxib previously lacked any indication for acute use. The Committee approved the revised COX-2 inhibitor criteria for all COX-2 inhibitors (celecoxib, rofecoxib, valdecoxib), which eliminate the duration of treatment requirement. Relatively few prescriptions for short-term therapy with COX-2 inhibitors are submitted to the NMOP.

Valdecoxib will be available from the NMOP as soon as the new PA criteria are implemented.

Etanercept (Enbrel) – The Committee added psoriatic arthritis to the prior authorization criteria for etanercept (Enbrel), in response to the FDA's recent approval of this indication.

Anakinra (Kineret) – The Committee established prior authorization criteria for this new once-daily, subcutaneous

NMOP Prior Authorization Criteria for COX-2 Inhibitors (Celecoxib, Rofecoxib, Valdecoxib)

Benefit coverage NOT provided for:

- Concurrent anti-inflammatory therapy with any NSAID or aspirin at doses > 325 mg per day, or
- The prevention of colon cancer, or
- The prevention or treatment of Alzheimer's disease

Benefit coverage provided for:

- Patient has previously failed an adequate trial with at least two different NSAIDS,

  OR

- COX-2 therapy AND high risk for NSAID-induced gastropathy OR use of a NSAID could result in destabilization or risk. Identified by any of the following:
  - Concurrent oral corticosteroids, anticoagulants, antiplatelet agents
  - History of PU
  - History of NSAID related ulcer
  - History of clinically significant GI bleeding

- Hereditary or acquired coagulation defect
- Age 65 years or older

interleukin-1 receptor antagonist product, approved in Nov 2001 for the reduction in signs and symptoms of moderately to severely active RA in adult patients who have failed one or more disease modifying antirheumatic drugs (DMARDs)
Anakinra has a mechanism of action similar to the TNF receptor antagonist etanercept (Enbrel). However, it differs from etanercept in its FDA-approved indications and therefore requires a separate PA. The Committee voted to adopt the Merck Medco criteria currently in place. In addition, given the existing quantity limits for etanercept and the similarity of the two drugs, the Committee established the same quantity limits for anakinra: a 6-week supply in the NMOP and a 4-week supply in the retail network

Click here to view the anakinra PA criteria on the PEC website. Anakinra is now available from the NMOP. The PA form for anakinra will be posted on the PEC website as soon as possible; in the meantime, the NMOP will contact providers by telephone and/or provide a prior authorization form by fax to complete the prior authorization process.

Controlled distribution of peginterferon alfa 2b (PEG-Intron; Schering) – The distribution process of peginterferon has been complicated due to unexpected demand, but a formal understanding with Schering has been reached. Currently, any new patients will go onto a waiting list. The wait is expected to be one to two months. All current patients will be provided product to complete their course of therapy. The current distribution process is outlined below:

- New patients should be instructed to call the Schering 800 number to get on the waiting list. The patient will be called when it is their turn to move off the list and be instructed to take their prescription to the MTF pharmacy. All new starts, as they move off the wait list, will receive product via a drop-ship to MTF mechanism, which will be billed through Prime Vendor.
- Any current patients should complete their therapy by continuing to use their current mechanism for acquiring the drug. If the patient was enrolled into the “Assured Access” program and assigned an identifying number, they should complete their course using that mechanism. Sites that have been getting the Peg-Intron drop-shipped without registering the patient should continue to do so. As the current patients using Assured Access identifiers complete their therapy, the need for using the numbers will also go away.
- The PEC will provide a monthly report to Schering regarding the number of MTF patients receiving PEG-Intron so Schering can reconcile this with the amount of product shipped. If an imbalance occurs, the PEC will clarify the situation by contacting the MTFs involved directly.
- LCDR Ted Briski (Ted.Briski@amedd.army.mil) is the PEC point of contact for

distribution issues.

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Advair

Will Ease of Use Improve Compliance & Outcomes?

CDR Denise Graham, MSC, USN
Navy Pharmacy Officer, DoD Pharmacoeconomic Center

At its last meeting in Feb 2002, the DoD Pharmacy & Therapeutics Executive Council approved the addition of all strengths of Advair (fluticasone/salmeterol) to the Basic Core Formulary (BCF) after considering its safety, tolerability, efficacy, price and other pertinent factors. Pertinent factors included the drug's place in therapy, recommendations of the DoD/VA Asthma Clinical Practice Guidelines, usage trends within the drug class, the percentage of MTFs that have Advair on their formularies, and input from MTF providers.

This article provides data on the comparative usage of Advair, Flovent, and Serevent in MTFs and the retail network, reviews provider opinion concerning the potential humanistic impact of using Advair vs. two separate inhalers, and addresses safety concerns regarding the treatment of exacerbations in patients on Advair.

MTF and Retail Points of Service Are Treating Increasing Numbers of Patients with Advair…

- Fluticasone and salmeterol are on the BCF as individual agents. As shown in the following graph, prescription fills for Advair are rising steadily at MTFs (up 60% from Jul 01 to Dec 01), while usage of the individual agents is flat or declining slightly.

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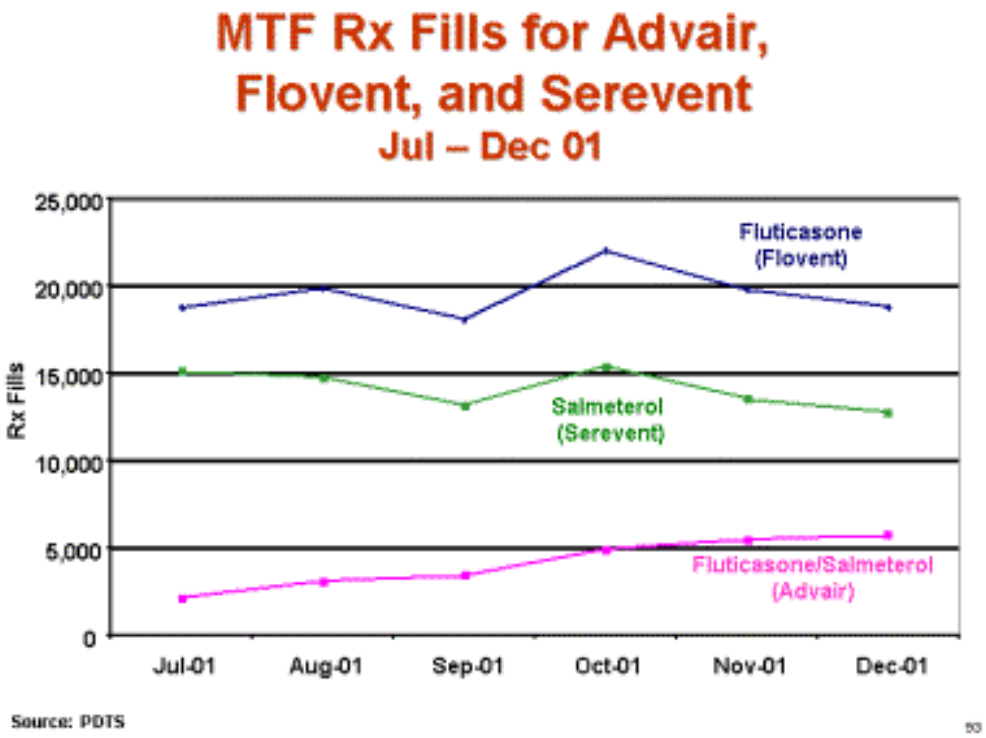
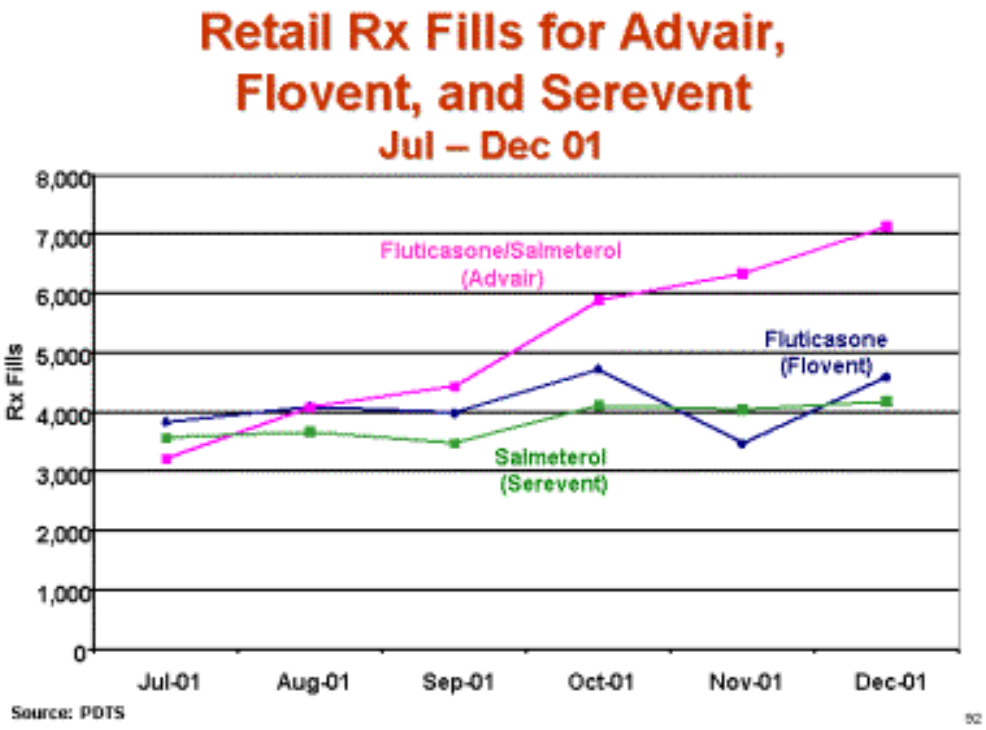


- Prescription fills for Advair are rising even faster in the retail network pharmacies (prescription fills more than doubled from Jul 01 to Dec 01).



…Which May Improve Humanistic Outcomes

Many providers commented that Advair is likely to result in improved patient satisfaction and compliance, which may improve effectiveness. Others noted that the combination product

prevented premature discontinuation of the inhaled corticosteroid due to patients attributing the benefits of treatment solely to the quick-acting beta-agonist. Of 63 providers responding to a survey regarding addition of Advair to the BCF, 56 were in favor, 4 were opposed, 3 were indecisive. Representative comments from providers:

- "The greatest benefit would be to our teenage population. The death rate of asthma in children has risen 150% between 1980 and 1996 – the age group with the highest mortality is 15-24 years of age. Asthma deaths today are preventable and we need to support combination therapy of inhaled corticosteroids and long-acting beta-agonists."
- "Advair administration is 1/20 of the time it takes to use the 2 separate inhalers. How could this not enhance compliance?"
- "Compliance with asthma controller medication decreases when more than one inhaler is used. Advair offers mandatory combination therapy and a single inhaler of 1 puff twice a day (vs. 2 inhalers, 4 puffs twice a day)."
- "Nine studies have proven that the addition of a long acting beta-agonist is superior to doubling the dose of inhaled corticosteroid (ICS) in the treatment of uncontrolled asthma in the patient already on an ICS."
- "The evidence also suggests that long acting beta-agonists should never be used as mono-therapy and should always be used in conjunction with ICS."

My Patient is on Advair: What About Exacerbations?

Does Advair have any specific safety concerns compared to its individual components? The safety and tolerability of the individual components of Advair are similar to the combination product at equivalent doses. However, one specific safety concern regarding this single inhaler combination product is the fixed dosage of salmeterol. The Council addressed this concern at its February meeting as a result of provider comments, although the topic was not covered in the minutes of the meeting.

The Asthma Action Care Plan from both the National Heart, Lung, and Blood Institute Expert Panel Report 2 and the DoD/VA Asthma Clinical Practice Guideline calls for an increase in the inhaled corticosteroid dosage if the patient goes into the yellow zone because of declining peak flows, increased rescue inhaler use, or increased asthma symptoms. In order to prevent the need for oral prednisone during exacerbations, the provider may desire to increase the dose of the inhaled corticosteroid (ICS). However, increasing the fluticasone dose by giving more than 1 puff of Advair twice a day will also exceed the recommended dosing of the salmeterol component, which could lead to $ß_2$ agonist toxicity (tremor or arrhythmia). This can be overcome by adding a separate inhaler of fluticasone during acute exacerbation periods.

For moderate and severe persistent long-term control, the DoD/VA Asthma Clinical Practice Guideline recommends an ICS plus an inhaled long-acting $ß_2$ agonist. The guideline does not specifically address patients on Advair. Space is provided on the Asthma Action Care Plan for a provider to make alternative recommendations to patients on Advair. Providers should instruct patients not to double or increase their Advair dose in response to exacerbations and should

caution patients not to use another long-acting $ß_2$ agonist with Advair.

What's the risk if patients do make a mistake and double up on their Advair rather than using a separate fluticasone inhaler, inadvertently receiving 100 mcg of salmeterol instead of 50 mcg? An recent article from Glaxo SmithKline's UK division, published in the Dec 2001 Annals of Allergy, Asthma, and Immunology, addressed this question by analyzing 10 single-dose and 9 chronic-dose studies that included a salmeterol 100 mcg treatment arm. Based on the pooled analysis, authors concluded that the systemic effects of salmeterol 100 mcg were of doubtful clinical relevance and that inadvertently doubling doses was unlikely to result in adverse effects. [Shrewsbury S, Hallett C. Salmeterol 100 microg: an analysis of its tolerability in single- and chronic-dose studies. Ann Allergy Asthma Immunol 2001;87(6):465-73.]

Q. Does using a separate inhaler of fluticasone for exacerbations in patients on Advair cost more?

A. Since there is no reason to expect that patients on Advair are more likely to have exacerbations than patients on individual fluticasone and salmeterol inhalers, the cost of the additional doses of fluticasone needed to manage exacerbations should be similar in both groups.

MAJ Barb Roach has been kind enough to put together a number of sources for educational, information and/or teaching materials on asthma and/or Advair (see table below). She also reports that she has contacted Major Geralyn Cherry at the MEDCOM Quality Management Office regarding revisions to the asthma guidelines to contain specific information for patients on Advair. In the meantime, however, MTFs may wish to revise their individual asthma action plans.

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Sources for Educational, Information and/or Teaching Materials on Asthma and/or Advair

I. DoD/VA Asthma Clinical Practice Guidelines can be downloaded on line at www.cs.amedd.army.mil/Qmo/asthfr.htm

- These guidelines were launched in 2000, but completed in 1999.

II. NHLBI* Asthma Guidelines can be downloaded on line at www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm

- The most recent update of these guidelines was 1997.
- Component 3 deals with Pharmacologic therapy (starts on PDF p. 57)
  - Figure 3-1 summarizes long-term control medications regarding their general indications, safety and therapeutic issues (PDF pp. 61-63).
  - Figure 3-2 summarizes quick-relief medications regarding their general indications, safety and therapeutics issues (PDF pp. 64-65).
  - Figure 3-5a summarizes the usual dosages for long-term control medications (PDF

p. 86).
- Figure 3-5b (PDF p. 88) lists estimated comparative daily dosages for the various inhaled corticosteroids.
- Figure 3-5d (PDF p. 91) lists the usual dosages for quick-relief medications.
- The University of Iowa has reformatted the NHLBI guidelines into a much friendlier presentation than PDF on their Virtual Hospital website at www.vh.org/Providers/ClinGuide/AsthmaIM/QuickRef.html#Patient%20Education

**NHLBI=National Heart, Lung and Blood Institute*

III. NHLBI COPD Guidelines can be downloaded on line at www.goldcopd.com

- These guidelines were launched in April 2001.
- This guideline is noted mainly to remind providers that inhaled corticosteroids are **NOT** considered as primary therapy for COPD, and Advair would **NOT** be a good choice for many of these patients.

IV. GlaxoSmithKline has asthma information online for providers and patients at www.ibreathe.com, with more specific Advair materials at www.advair.com.

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Barb's Barbs

Generics vs. Brand Names

MAJ Barbara Roach, USAF, MC
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Q. (that I made up since no one has volunteered a question yet) *Our MTF wants us to use generic drugs whenever possible. These penny-pinchers don't seem to understand that there's a HUGE difference between any brand-name drug and its generic AB-rated "equivalent". You never know what's actually in the generics. They don't have the same potency as the brand-name items. Heck, they aren't even the same from batch to batch from what I learned in medical school. Generics just plain have a bad name and our patients deserve "the best." Don't you agree, Dr. Barb?*

A. Well, yes and no (a big surprise with that answer, huh?) Let's take it a piece at a time.

Q. What does the FDA mean by AB-rated and therapeutically equivalent?

A. Straight from the preface to the FDA's "Orange Book":

> "Drug products are considered to be **therapeutic equivalents** only if they are pharmaceutical equivalents and **if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling**. Drug products are considered **pharmaceutical equivalents** if they contain the same active ingredient(s), are of the same dosage form, route of administration and are identical in strength or concentration (e.g., chlordiazepoxide hydrochloride, 5 mg capsules)…but they may differ in characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration

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> time, and, within certain limits, labeling." **Drug products for which actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence are designated AB.** [1]

Q. *Well, the FDA has never bothered to address this equivalency concern to providers, have they?*

A. On the contrary; go to http://www.fda.gov/cder/news/nightgenlett.htm and you can read the entire letter they sent out to providers in 1998. In the letter, they specifically mention that "To date, there are no documented examples of a generic product manufactured to meet its approved specifications that could not be used interchangeably with the corresponding brand-name drug." [2] This letter was sent out in response to concerns about narrow-therapeutic index drugs such as carbamazepine, but can apply to any AB-rated generic.

Q. I'll bet no one has ever bothered thinking about the social problems associated with switching a medication. If the patient seizes after a switch from Tegretol to carbamazepine, you have a major problem on your hands.

A. Again, from the FDA letter to providers:

> "Questions have been raised in the past, as well, regarding brand name and generic products about which there could be concern that quality failures might represent a public safety hazard. FDA has performed post-marketing testing on many of these drugs to assess their quality. In one instance, more than 400 samples of 24 marketed brand name and generic drug products were tested and found to meet the established standards of purity and quality. **Because patients may pay closer attention to their symptoms when the substitution of one drug product for another occurs, an increase in symptoms may be reported at that time, and anecdotal reports of decreased efficacy or increased toxicity may result.** Upon investigation by FDA, no problems attributed to substitution of one approved drug product for another has occurred."[2]

My interpretation of this is -- if you definitely don't want something to work, you (the provider or pharmacist) will find a way to make it look bad. Even it the true believer is proven wrong, well, you can't convince someone who doesn't want to be convinced. The Flat Earth Society still exists. [3]

Q. Did pharmacists ever get a similar letter?

A. Go to http://www.fda.gov/cder/news/ntiletter.htm where you can read the letter from 1997 that was sent in response to the National Association of Boards of Pharmacy when they went before Congress in an attempt to halt therapeutic substitution. It reinforces the point that the term therapeutic equivalence "indicates that they can be substituted with the full expectation

by the patient and physician that they will have the same clinical effect and safety profile as the innovator drug." [4]

Q. Has anyone stopped to think about all the cost of extra lab testing that will need to be done when switching from a brand to a generic? Answer that ONE bucko.

A. Again from the FDA letter to providers [2]:

> "Based on FDA's determination of therapeutic equivalence between generic and innovator drug products, the FDA concludes that:
>
> - **Additional clinical tests or examinations by the health care provider are not needed when a generic drug product is substituted for the brand-name product.**
> - Special precautions are not needed when a formulation and/or a manufacturing change occurs for a drug product provided that the change is approved according to applicable laws and regulations by the FDA.
> - **As noted in the "Orange Book," in the judgment of the FDA, products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is brand name or generic drug product.**
>
> It is not necessary for the health care provider to approach any one therapeutic class of drug products differently from any other class, when there has been a determination of therapeutic equivalence by FDA for the drug products under consideration." [2]

Additionally from my viewpoint—if there's anyone on the planet that can actually come up with a valid way to measure cost of switching in the DoD—please pass the secret on to us. If you can actually find out something as simple as the "real" **COST** of a lab test in DoD, you're doing really well.

You can find everything the FDA has to say about therapeutic equivalence by going to http://www.fda.gov/cder/orange/default.htm or the Orange Book table of contents at http://www.fda.gov/cder/ob/docs/preface/ectablec.htm

Now for a little history...

Q. Have pharmacists always been able to make generic substitutions?

A. The 1950s were noted for an explosion in the growth of new drugs and was the beginning of generic substitution for brand name medications by pharmacists. It should come as no surprise to anyone that this resulted in a pharmaceutical manufacturers trade group pressing states to pass laws forbidding replacement of a prescribed brand name product. With the

1960s thalidomide disaster Congress added a requirement for efficacy standards for new medications. Costs began to rise in the 1970s and this provided reason to repeal the previous laws forbidding generic substitution. By the 1980s health care constituted one-eighth on the US Gross Domestic Product and we saw the dramatic rise of HMOs which pretty much maxed out their ability for easy cost containment by the 1990s. [5]

Q. Doesn't the FDA require generics to meet the same standards as the innovator drug? If so, why is there all this skepticism about the safety and efficacy of generics?

A. Pre-1938 drugs and those grandfathered in before the 1962 Waxman-Hatch amendment have not necessarily been evaluated for safety and efficacy and there are no set standards for them. This fact has probably fueled a lot of the suspicion about generic equivalence. Many of these drugs have been reformulated from their original and caused problems with bioavailability. This hasn't just been a problem with the generics. Pre-1938 drugs such as Synthroid were reformulated and had significant problems with dosing afterward. Additionally, I suspect much of the problem can be attributed to what is routinely referred to as the Generic Scandal of 1989. One pharmaceutical company noted increasing difficulty getting their generic equivalents approved by the FDA. They hired a private detective who uncovered numerous problems including 1) several FDA employees who had been taking bribes from pharmaceutical companies to get their drugs approved; 2) false data submitted to the FDA for approval of generic drugs by several firms (one of the companies actually submitted the brand name maker's drug as its own to get swift approval); and 3) some generic companies had violated good manufacturing practice regulations. [6] [7] These concerns were corrected when the US Pharmacopeia required all manufacturers to use a more reliable method to monitor potency of their drugs. [8]

Q. Well, what **IS** *the FDA standard for bioequivalence in order for a generic to be considered a therapeutic equivalent to the innovator drug?*

R. "The standard bioequivalence study is conducted in a crossover fashion in a small number of volunteers, usually with 24 to 36 healthy normal adults. Single doses of the test and reference drugs are administered and blood or plasma levels of the drug are measured over time. Characteristics of these concentration-time curves, such as the area under the curve (AUC) and the peak blood or plasma concentration (C_{max}), are examined by statistical procedures.

Bioequivalence of different formulations of the same drug substance involves equivalence with respect to the rate and extent of drug absorption. **Two formulations whose rate and extent of absorption differ by -20%/+25% or less are generally considered bioequivalent. The use of the -20%/+25% rule is based on a medical decision that, for most drugs, a -20%/+25% difference in the concentration of the active ingredient in blood will not be clinically significant."** [9] Of interest, when the first 224 drugs approved post the 1962 Waxman-Hatch amendment were tested, there was only a 3.5% difference in bioavailability observed between the generics and the innovator drugs. [10] This should reinforce the fact that generics have to meet the same standard as the innovator drug, and they are not of lower quality.

Q. Has anyone surveyed pharmacists to document their views on generic medications?

A. Yes. According to an APA survey,[11] pharmacists as a group generally accept generic medications. The drugs that seemed to be of most concern were the "narrow therapeutic index drugs", also referred to as "critical dose drugs," partly because a number of these predated the initial publication of *Approved Drug Product with Therapeutic Equivalence Evaluations* (the *Orange Book*), which identifies therapeutically equivalent products. The most important factors pharmacists cited for selecting a product were quality, price and supplier consistency.

Q. Do patients find generic substitution acceptable?

A. According to the APA survey of pharmacists noted above, 72% of patients accepted generic medications when the pharmacist recommended them. [11] Presentation is everything. If the pharmacist suggests the drug is inferior, the patient is likely to accept this advice. If the pharmacist suggests the drug is an acceptable substitute for a brand name drug, the patient will also likely agree. Likewise, when a physician suggests generic substitution to a patient, 75.8% of patients agree. [12]

Q. Do major professional pharmacy organizations have documented policies regarding generic substitution?

A. Some do and some don't. The American College of Apothecaries and Healthcare Distribution Management Association have no written policy. American Pharmaceutical Association (APhA), American Society of Health-System Pharmacists (ASHP) and National Community Pharmacists Association (NCPA) all have policies that support appropriate therapeutic substitution by pharmacists. [11]

Q. Has anyone surveyed physicians regarding their attitude about generic substitution?

A. Yes. "Significant differences were found between the pro-substitution and anti-substitution groups with respect to beliefs about and experiences with generics and knowledge of the Food and Drug Administration bioequivalency standards. Of particular significance was the low percentage (17%) of physicians who correctly identified the Food and Drug Administration standards for bioequivalency." [12] Both pro-substitution and anti-substitution groups felt that an acceptable degree of variation in bioavailability for medications should be 11% for most medications and 5% for critical dose medications. This is quite different from the –20% or +25% that the FDA uses.

Q. Are there many drugs that have been available prior to 1938 and can bypass the current FDA safety and efficacy standards?

A. As of 1996, I found a reference stating there were 240 pre-1938 drugs available and that only 45 of them had submitted safety and efficacy data to the FDA in the form of New Drug Applications. [13]

Q. What about levothyroxine? This has to be the oldest drug on the planet. What is all the bruhaha about levothyroxine lately and specifically Synthroid?

R. You're right about the length of time this drug has been available. It predates the Waxman-Hatch amendment and has been on the market since 1955 when Synthroid was introduced. The problem was brought to the FDA's attention by the nonprofit organization Public Citizen. They urged the FDA to begin a safety and efficacy review on all pre-1938 drugs currently on the market. Synthroid was the one that caught their attention due to a glossy marketing brochure that proclaimed "No proven bioequivalent product", "There is no substitute for Synthroid" and "No adequate and well-controlled studies have demonstrated bioequivalence amongst levothyroxine sodium products." Public Citizen noted that since the FDA had not established any bioequivalence standards for these pre-1938 drugs that Synthroid was able to capture 85% of the market by taking advantage of this void.

A real brief synopsis of what also set the frenzy off was a journal article whose publication was blocked by Knoll pharmaceuticals (who manufactured Synthroid at that time). UCSF had done a study funded by Flint Laboratories (later known as Knoll), comparing the bioequivalence of four brands of levothyroxine, including its own formulation, Synthroid. The research showed that the two brand name levothyroxine formulations and the two generic formulations were ALL bioequivalent and the manuscript was submitted to JAMA for publication. Knoll threatened the researcher (Betty Dong) and the University with a lawsuit if the article were published—they had had the authors sign a gag clause prior to starting the research and no one had noticed this at the University. UCSF was ready to stand behind their investigators in the name of Academic Freedom—until it was apparent that the company would go forth with a lawsuit. Then they let the researcher know they were on their own and the paper was withdrawn from publication one week before it was to go to print. Knoll also published an article attempting to discredit the Dong study that didn't go to print.

The FDA met in Jan 1997 and determined that the original UCSF article was well done and the attempt to discredit it by Berg/Mayor and Knoll was misleading. Knoll agreed to allow publication of the original article. [14] A class action lawsuit was filed due to the attempt to prevent publication of the article. [15] As a result of all this, a notice was placed in the Federal Register in August 1997 which stated "no currently marketed orally administered levothyroxine sodium product has been shown to demonstrate consistent potency and stability and, thus, no currently marketed orally administered levothyroxine sodium product is generally recognized as safe and effective." [16] [17] The companies were given until August 14, 2000 to conduct safety and efficacy studies and submit their NDAs (new drug applications). Manufacturers began their studies and submitted their data for NDAs—with the exception of Knoll Pharmaceuticals.

The deadline was extended to August 14, 2001. There was much wailing and gnashing of teeth, an eternal flurry of FOIA (Freedom of Information Act) requests and other delay tactics but in the end, the FDA told Knoll that they were NOT exempt from filing. During this study time, all drugs were left on the market as the FDA noted that levothyroxine sodium products are medically necessary and because no alternative drug is relied on by the medical community as an adequate substitute. [18] [19]

But wait! There's more. Effective March 2, 2001, Abbott Laboratories of Abbott Park, Illinois, in the United States, acquired the pharmaceutical business of BASF, which included the global pharmaceutical operations of Knoll. [20] This is now the 4th company to be caught up in the Synthroid saga. Abbott submitted the NDA for Synthroid in August 2001, and the FDA is reviewing it at the present time. The FDA has also established a "phase down" plan for drugs that have yet to receive FDA approval (i.e., Synthroid) with a final stop date of August 14, 2003. (Manufacturers who did not have an application pending as of August 14, 2001 had to cease distribution immediately that day.) Unithroid was the first drug approved on August 21, 2000 and is now the drug to which others have to show bioequivalence. Levoxyl was approved May 25, 2001. [19]

Does it stop here? Of course not. Watson Pharmaceuticals, maker of Unithroid, was taken to court by Abbott for claims it made:

> "Specifically, the Court preliminarily enjoined Watson from making the following representations: (1) that the manufacturer of Synthroid violated the FDA's August 1997 Notice by failing to file an NDA for Synthroid; (2) that Synthroid is not safe and effective and that FDA's denial of the petition seeking GRAS/E [Generally Recognized as Safe/Effective] status for Synthroid demonstrates that Synthroid is not safe and effective; and (3) that the FDA's approval of Unithroid's NDA application means that it is a superior product to Synthroid and other levothyroxine products that have not yet received NDA approval. The Court also pointed out that it expresses no opinion on the safety and efficacy of the competing levothyroxine products, and that the determination of safety and efficacy is within the province of the FDA." [21]

Q. Are there any studies that compare brand names of levothyroxine in a head-to-head fashion?

A. Yes, there are several but we'll just look at a few of them. [22] One study sponsored by Boots Pharmaceuticals (later known as Knoll) proposed that the two drugs could not be considered bioequivalent because total T4 sampling done at different sampling hours (over a 48 hour period) demonstrated statistically significant differences. They also note statistically significant differences in AUC and maximum peak plasma concentration between the two formulations. These results however aren't very useful when one considers that the half-life of these drugs is 7 days—a little longer than the 48 hours testing period. This study was repeated by Baylor College [23] and they found that switching did not result in substantial clinical or laboratory changes in any individual patient. The researchers concluded that the two brands were interchangeable.

The major paper is the original one by Dong et al, which was finally published in 1997 and showed no difference between the bioavailabilities of Synthroid, Levoxyl, and two generic levothyroxine sodium preparations. It was a single-blind (the primary investigators were blinded), randomized, 4-way crossover trial in outpatients with known hypothyroidism. [8]

Q. So what is the bottom line on which thyroid medication should be chosen for any particular patient?

A. In the words of Dong et al:

> "There is no basis (other than cost) for preferring any of these preparations for new patients. For patients who wish to reconsider their choice of levothyroxine preparation, it is reasonable to discuss these options with their physician so that such a change can be monitored if clinical symptoms warrant. The lifetime cost savings are substantial after changing to a nonbranded product even if thyroid function tests are repeated. Routine assessment and monitoring of thyroid function tests are recommended irrespective of the actual brand of levothyroxine taken." [24]

Generics and the NMOP...

Q. How come the NMOP doesn't follow the same rules about generics as the MTFs? Seems unfair.

A. Civilian mail order operations have to follow the laws of the state they're dispensing from. Before TRICARE for Life stood up, the volume was such that Merck-Medco Managed Care (MMMC) only needed to use New Jersey for dispensing medications (with a few exceptions). Now that the volume has increased, they dispense also from Nevada and Pennsylvania and are subject to following those state laws. DoD cannot supercede state law when using a civilian operation such as Merck-Medco.

Merck-Medco uses an automatic switch program which allows generic substitutions under certain circumstances (e.g., an AB-rated generic exists; the change is financially prudent; the plan (in this case DoD) allows the switch to occur; state law requires generic substitution).

Moral of the whole story

- You can't trust a brand-name drug simply because it has a brand-name.
- You can't point to pre-1989 generic problems and use this as the basis for your decisions today.
- The brand names of today don't immediately become useless when their patents run out.
- You can probably save your MTF a few bucks with no degradation in patient care by looking at your specific brand-name/generic drug usage and detailing your providers.

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Contract Compliance

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DoD/VA Mandatory Source Contracts for Generics

LCDR Ted Briski, MSC, USN
Navy Pharmacy Officer, Director of Contracting Activities, DoD PEC

The Department of Defense (DoD), in conjunction with the Veterans' Administration (VA), invests significant time and resources into formulating the most appropriate procurement strategy for pharmaceutical agents used by our two healthcare delivery systems. The DoD Pharmacoeconomic Center (PEC) works closely with the Defense Supply Center Philadelphia (DSCP), the VA Pharmacy Benefit Management office (VA PBM), and the VA National Acquisition Center (VA NAC) to provide the lowest possible prices to our facilities.

How the Contracting Process Works

First, the DoD Pharmacy and Therapeutics Committee (DoD P&T) reviews the clinical data and makes an evidence-based decision that defines the parameters for potential contracting. As part of its P&T Committee support function, the PEC uses a process known as a "STEPO analysis" to determine the therapeutic interchangeability of drugs within a class. (STEPO = Safety, Tolerability, Efficacy/Effectiveness, Price/Cost, Other Factors.) This analysis is based on a critical review of the medical literature as well as assessment of the performance of agents in clinical practice. (Watch for a more in-depth discussion of the STEPO process in next month's PEC Update.)

The clinical determination of the P&T Committee, combined with utilization and market factors, determines the ultimate procurement strategy. Strategies range from very prescriptive closed-class contracts (currently, the only closed classes are "statins" and non-sedating antihistamines) to blanket purchase agreements and incentive price agreements.

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The vast majority of contracts end up being mandatory source contracts for one brand of a given generic entity (generic contracts). These are fixed price 5-year contracts that must be renewed by the government annually. Although these drugs may be on the BCF, the contracts themselves do not usually include a requirement for BCF status.

While the DoD typically does not realize a substantial cost savings from mandatory source generic contracts, noncompliance with these contracts/agreements does degrade our ability to negotiate best price. More importantly, the lack of uniformity of product appearance that can result from facilities obtaining different brands of the same generic entity at different times can compromise patient safety and create potential for patients to not adhere to their prescribed medication regimens. The lack of contract compliance, especially with generic contracts, raises several questions:

1. Is this simply a situation where the MTF supply person is unaware of the contracted agents? A current list of existing contracts is available on the DSCP's DMM Online website. A link is also available on the National Contracts page on the PEC website.
2. Is contract noncompliance a result of the product being unavailable from the prime vendor? Any pattern of product unavailability should be reported to MAJ Cheryl Filby at DSCP (paa3015@dscp.dla.mil).
3. Is there some other compelling reason causing MTFs to order off contract? If so, we need your help to understand the issue(s). Information can be sent to LCDR Ted Briski at the PEC (Ted.Briski@amedd.army.mil).

For those who knowingly and purposely order off-contract, I offer the following: DoD policy plainly states that BCF drugs are meant to be the primary and uniformly available agent(s) used in a specific drug class. The BCF is designed to meet the clinical needs for the majority of primary care patients. Most BCF agents are available to MTFs under contract/agreement terms that are favorable to the government. Contract noncompliance may offer some short-term benefit to specific MTFs, but it hurts the system as a whole. It is not possible for individual MTFs to negotiate prices that may be obtained using the total requirements of the DoD and VA. Some pharmaceutical companies attempt to game the system by undercutting contract prices in select locations. It is a disservice to your colleagues and customers to knowingly collude with industry to undermine our overall ability to effectively negotiate the best price for the entire healthcare delivery system.

Overall our procurement program has been a huge success. It has succeeded because of the hard work done at the local level to support evidence-based formulary decisions and the subsequent procurement strategy to assure affordability for our MTFs. We salute your efforts and encourage frequent contact with the PEC staff so we may better understand the complex issues you face daily.

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On Line Patient Profiling in CHCS

By Sonya Edom, PDTS CSSC Help Desk Manager

On Line Patient Profiling is a new CHCS option for providers or pharmacy personnel to view the entire patient profile (combined CHCS and PDTS profile) for patients registered in their CHCS system. This option allows viewing of all prescriptions filled at any of the three MHS points of service (MTFs, NMOP, retail network pharmacies). There are currently 38 CHCS Host sites utilizing On Line Patient Profiling.

Critical Data Elements Required - Critical patient data elements must be available to send the request to PDTS:

sponsor's SSN

DDS (DEERS Dependent Suffix)

FSN (Family Sequence Number)

The DDS and FSN are **NOT** entries in CHCS by local staff. These are CHCS fields auto-populated by DEERS. To ensure these fields are correctly populated, especially for new patients, complete a DEERS check at time of registration.

Accessing the Profile for Pharmacy Users - To access the On-line Patient profile for **PHARMACY** follow menu path **PHR>OPM>PM>PRI**. Enter the **PATIENT** name at the **SELECT PATIENT /RX#** prompt. Then choose **P** for combined CHCS and PDTS profile. Choose the number corresponding to the time frame (30 days, 60 days, etc.) you wish to view. The profile can be viewed on the screen, sent to a printer or sent to your CHCS Mail Box. If a response is not received with in 6 seconds then CHCS will display "No profile response received from the PDTS" and will then allow the user to send the profile to the mailbox or a printer when connectivity has been reestablished.

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Accessing the Profile for Clinical Users - To access the On line Patient Profile for **CLINICAL** users, after entering in **ORE**, enter the patient name and requesting location. At the Action prompt enter **DPRX** (Display PDTS Patient Profile). Choose the number corresponding to the time frame (30 days, 60 days, etc.) you wish to view. The profile can be viewed on the screen, sent to a printer or sent to your CHCS Mail Box. If a response is not received within 6 seconds then CHCS will display "No profile response received from the PDTS" and will then allow the user to send the profile to the mailbox or a printer when connectivity has been reestablished.

What the Profile will look like - When viewing the patient profile through the On-line patient profile query, you will first see the CHCS patient profile, followed by the PDTS patient profile. While the PDTS central patient profile has all of the prescriptions filled in that time frame, the information represented will be only the most recent fill for that particular prescription coming from outside of the CHCS HOST site. PDTS sends the Rx number, drug name, pharmacy name, physician name (if on file), quantity, days supply, new or refill code and date filled. In the New or Refill column a ZERO (0) is an indication of a NEW fill; 1,2,3,4, etc., indicates the refill.

Response time - During alpha testing at Wright Patterson AFB, response time back to the user was between 2 and 5 seconds. The average turn around time at PDTS was less than 1 second. Please keep in mind that the length of time it takes to get a profile back can be dependent upon the length of time requested as well as the length of the patient profile.

PDTS Standard Reports

By COL (Ret) Roger Williams, PDTS CSSC Clinical Support Supervisor

In the last *PEC Update* we gave you a brief introduction to the new PDTS Report Request Form and a reference to a listing of the standard reports currently available. I would like to use this issue to provide you with a more in-depth discussion of standard reports.

Many of the standard report names are self-explanatory and differ from one another only slightly. By the nature of being standard reports, there is no flexibility in the output format and there are only a few variables available to tailor your report to a specific need. All standard reports allow you to select the population pool you wish to pull the data from and the dates you wish the report to cover. Some reports also give you the option to have the data pulled by age stratification and to present the drugs either by generic or brand name.

Once you have decided which standard report will give you the information you need, you must then decide which population pool you want to pull the data from and the dates you want the report to cover. In most cases, the dates for the report will not be a problem. Most often you will ask for data from a specific month, quarter or any start and end date that will meet your requirement. When selecting your end date, please keep in mind that the data warehouse from which the data is retrieved is updated every weekend, so there may be times when a report will have to be delayed until the last day of the month has been moved over to the data warehouse.

When it comes to selecting a population pool, however, there can be some confusion as you have several options. Below I have listed the options, the population pool they represent, and additional options you may need to select.

PDTS Customer Service Support Center Contact Information

NEW! - The PDTS CSSC has a new e-mail address for questions, comments, concerns, or report requests:

PDTS@cen.amedd.army.mil

Drop us an e-mail we will respond via e-mail or call you within 1 business day.

Or call the PDTS CSSC at:

- DSN: 471-8274
- Toll-free commercial: 1-866-275-4732 (1-866-ASK4PEC)
- Local commercial (San Antonio): (210) 221-8274
- OCONUS: (AT&T access code)+866-275-4732

Hours: 24 Hours a Day, 7 days a Week

Department of Defense (DoD) - In this option you are pulling data from all dispensing locations in all three points of service: MTFs, MCSCs, and NMOP. It is the most inclusive option available. There are no additional options to be selected to define this population pool.

Service Category - When you select this option you can pull from any of the three points of service (MTFs, MCSCs, NMOP) or any combination of the three. Along with this option you must also select at least one

TRICARE region, a combination of regions or all regions to define your population pool.

Individual MCSC - This option gives you the opportunity to narrow your point of focus to a specific MCSC. You can select any one MCSC or any combination of two or more MCSCs. In this option you must further select the corresponding TRICARE region or the combination of regions that match your MCSC selection to correctly define your population pool.

Region - This option is similar to the Service Category option but in reverse. You first select a TRICARE region or combination of regions and then you select the point of service to define your population pool. You would get the same data with either option.

Host - With this option you are limited to data only from MTFs. When you select this option you get a list of all CHCS Hosts and you can choose any one or a combination of Hosts. As expected, this option pulls data from all MTFs supported by the CHCS Host selected. There are no additional options to be selected to define this population pool.

Site MTF - This option lets you narrow your focus to just a specific MTF or a group of MTFs. As such, a list of all MTFs where there is a dispensing pharmacy appears and one or more MTFs can be selected. This option will pull data from all the dispensing locations within the selected MTF. There are no additional options to be selected to define this population pool once an MTF has been chosen. **NOTE:** If more than one dispensing location utilizes the same NCPDP # then the data will be combined.

Pharmacy - This final option allows you to focus on an individual dispensing location within an MTF, a specific retail network pharmacy, or a specific dispensing location within the NMOP. As in the other options, you have the opportunity to select any one location or a combination of two or more locations. There are no additional options to be selected to define this population pool once a pharmacy has been chosen.

Hopefully this short primer on standard reports will help you understand a few of the intricacies of requesting data for your area of interest. In future issues we will highlight specific standard reports and get deeper into the PRN report request process. Having said all this, we certainly don't expect you to become an expert on PDTS reports. We at the Customer Service Support Center are available at any time to assist you in any way possible, as we want to ensure the product we provide is of value to you, our customer.

Data Integrity

By Hector Morales, PDTS CSSC Day Shift Supervisor; ACS Task Lead

Data Integrity is one of the most essential elements to ensure accurate and beneficial clinical information goes to the providers and pharmacy personnel from PDTS. However, on a daily basis PDTS receives numerous prescription transactions with inaccurate days supply, metric quantity or both.

Our analysis has isolated the problem to one of three issues:.

First, when a prescription is entered the quantity is input incorrectly due to confusion about the package size and conversion of quantity to metric quantity.

The package size field in the drug file is misunderstood and used incorrectly.

If the default sig in the drug file is built incorrectly, an incorrect quantity or days supply can be auto-populated. These problems can create drug-drug interactions and therapeutic duplications that affect not only the direct care system, but also the MCSCs and the NMOP contractor.

There is still an onslaught of discussion from the field about "all the noise" PDTS creates. Poor data integrity generates a significant portion of the noise by creating false clinical warnings. At times, this "noise" causes MTF providers and pharmacy staff to "ignore" PDTS warning messages without regard to the content and severity. This is not a beneficial way to handle the "noise."

I recently worked on a query listing the top 10 NDC numbers that were sent to PDTS with a day supply greater than 180 days. The result of this query shows two very distinct patterns:

> The first pattern is that some sites or branches of service have a policy to dispense certain classes of medications for a 6-month supply or greater. Two examples are birth control pills (BCPs) and anti-hypertensive medications.
>
> The second pattern is that days supply does not match quantity dispensed due to the data integrity issues brought up earlier in this article. For example, a prescription is sent to PDTS for a BCP with a metric quantity of 84 and a days supply of 365.

I have personally contacted the MTF pharmacy points of contract for PDTS or the chiefs of pharmacy to help solve data integrity issues. These discussions have been received with open arms. The individuals I spoke with have taken a closer look at the drug file; some of the changes made were to add default sigs correctly, correct the package size in the drug file, or even edit the label print name so there is a better understanding of what quantity to order.

In addition to looking at the days supply issues, I have also been looking at over-utilization DURs to analyze why over-utilization edits are created at the MTF level. It was discussed in the last *PEC Update* how over-utilization DURs are determined by PDTS. Since then, the tolerance level for over utilization screening has been increased to 333 percent.

Most MTFs have excellent data integrity—but there **ARE** a few exceptions. A large part of the over-utilization DURs are returned due to a quantity entered for a prescription using the intended "metric quantity" when that drug has a "package size" in the drug file, resulting in an inaccurate quantity sent to PDTS. For example, some pharmacies pre-pack cetirizine liquid in 120 mL bottles. In the drug file for cetirizine liquid, 120 is populated in the package size field. A prescription is entered for a **QUANTITY** of 120 mLs, making the **METRIC QTY** actually transmitted to PDTS 14400 mLs (120 times 120). This in turn causes the days supply to be auto-calculated improperly. Therefore, keeping all pharmacy personnel educated on medications containing package sizes in the drug file can help decrease the amount of unedited erroneous quantities sent to PDTS. Many pharmacies use a system where the label is looked at by at least two people (if not three) before it goes out the window, ensuring a quality check of everything. This ensures that the right drug is in the right bottle as well as that the quantity on the label was ordered properly.

If the issue of data integrity is viewed with strong interest from top management, these issues could soon be alleviated. Below is a small example of the Top 10 NDC report as well as the Over- utilization report. If you have any questions on any of this information, please feel free to call or e-mail the CSSC.

Days Supply

Generic Drug Name	Strength	Form	Days Supply	Metric Qty
CHLORHEXIDINE GLUCONATE	1.2MG/ML	LIQUID	365	480
CHLORHEXIDINE GLUCONATE	1.2MG/ML	LIQUID	365	960
NORGESTIMATE-ETHINYL ESTRADIOL	7-7-7	TABLET	365	2352
GUAIFENESIN/CODEINE PHOS	100-10MG/5	SYRUP	365	28800
GUAIFENESIN/CODEINE PHOS	100-10MG/5	SYRUP	365	120
COLESTIPOL HCL		GRANULES	365	1350

COLESTIPOL HCL		GRANULES	365	2700
NITROGLYCERIN	0.2MG/HR	PATCH TD24	365	2700
NITROGLYCERIN	0.2MG/HR	PATCH TD24	365	1800
IBUPROFEN	100MG/5ML	ORAL SUSP	365	14400

Over Utilization

DRUG NAME	Strength	Dose Form	Days Supply	Metric Qty
MILK OF MAGNESIA	400MG/5ML	ORAL SUSP	90	50374
PERIOGARD	1.2MG/ML	LIQUID	7	56760
PREMPRO	0.625-2.5	TABLET	30	2520
PREMPRO	0.625-2.5	TABLET	84	2352
TRANSDERM-NITRO	0.4MG/HR	PATCH TD24	90	2700
ZYRTEC	1MG/ML	SYRUP	30	56760
ZYRTEC	1MG/ML	SYRUP	30	11825
ZYRTEC	1MG/ML	SYRUP	30	70950

Top 50 Drugs for Jan & Feb 2002 by Point of Service

By Preston Hardy, PDTS CSSC, Clinical Support Coordinator

One of the many benefits of PDTS is the capability to review and compare prescription utilization by point of service. The last issue of the *PEC Update* included a table of the top 50 drugs (by prescription count) in each MHS point of service for the six-month time period, July 2001 - Dec 2001. This month's issue includes the same table for Jan 2002, and for February 2002, in Microsoft Excel format:

Jan 2002 MHS Top 50 Drugs by POS

Feb 2002 MHS Top 50 Drugs by POS

The first three tables in the files list the Top 50 drugs by prescription count dispensed at MTFs, the retail network, and the NMOP. Column headings are defined as follows:

- **Drug Description** - contains all strengths and dosage forms
- **Ranking** - from 1 (most dispensed) to 50 (least dispensed)
- **# of Rxs** - number of prescriptions dispensed
- **Qty. Disp**. - total quantity of measured units dispensed
- **Avg. Qty Per Rx** - average number of measured units per prescription
- **Avg. Days Supply** - average days supply issued per prescription
- **Unique Utilizers** - number of patients receiving a prescription for the listed drug from that point of service.

The fourth table compares the Top 50 drugs in MTFs against the same drugs in the retail network and NMOP. A blank cell means that the corresponding drug did not fall in the top 50 for that specific point of service.

THE PHARMACY DATA TRANSACTION SERVICE CUSTOMER SERVICE SUPPORT CENTER

The PDTS CSSC strives to provide world-class customer support to all Military Health System users while enhancing the operational effectiveness and ensuring the quality of information maintained within the Pharmacy Data Transaction Service.

As most are already aware, with the new contract award for TMSSC to the MHS Help Desk, PDTS CSSC has now consolidated with the PEC at Ft. Sam Houston, TX.

There are currently 22 outstanding individuals at the PDTS CSSC. If you would like to meet the entire PDTS CSSC team go to http://www.pec.ha.osd.mil/pdts/pdts_team.htm

If you would like to know how to reach one of our helpful staff members go to: http://www.pec.ha.osd.mil/pdts/support.htm

We are available to assist you 24 hours a day 7 days a week.

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Summary of Changes to the Basic Core Formulary and National Mail Order Pharmacy Formulary

Resulting from the 12-13 February 2002 meetings of the DoD Pharmacy & Therapeutics Executive Council and the DoD Pharmacy & Therapeutics Committee

1. BCF Changes

A. Additions to the BCF

1. Azithromycin (Zithromax) 250 mg tablets, does not require the Z-pak dosage formulation
2. Clopidogrel (Plavix)
3. Conjugated estrogens/medroxyprogesterone oral (Prempro) : all strengths (does not include Premphase)
   Fluticasone/salmeterol inhaler (Advair): all strengths
4. Levonorgestrel 0.75 mg (Plan B)

B. Deletions from the BCF - None

C. Changes and clarifications to the BCF

1. The current BCF listing for brimonidine tartrate ophthalmic solution was clarified to identify the new Alphagan P 0.15% formulation as the specific agent included on the BCF.
2. The current BCF listing for methylphenidate does not include dexmethylphenidate (Focalin)

2. NMOP Formulary Changes (For more information see minutes of the 13 February 2002 DoD P&T Committee Meeting)

A. Additions to the NMOP Formulary (See Appendix A of the minutes for details)

1. Valdecoxib tablets (Bextra; Pharmacia) – added to NMOP with PA criteria
2. Frovatriptan tablets (Frova; Elan) – quantity limits apply, see below

3. Desloratadine tablets (Clarinex; Schering-Plough)
4. Anakinra injection (Kineret; Amgen) –added to NMOP Covered Injectables List with PA criteria, quantity limits apply, see below
5. Triptorelin pamoate depot injection (Trelstar LA; Debiopharm/Pharmacia) – added to NMOP Covered Injectables List
6. Fondaparinux injection (Arixtra; Sanofi/Organon) – added to NMOP Covered Injectables List
7. Pimecrolimus 1% cream (Elidel; Novartis)
8. Diclofenac sodium topical gel (Solaraze; Sky Pharma)
9. Dexmethylphenidate tablets (Focalin; Novartis) – quantity limits apply, see below
10. Extended phenytoin sodium, 200 mg and 300 mg capsules (Phenytek; Bertek) – automatic line extension
11. Brimonidine tartrate ophthalmic solution (Alphagan P; Allergan) - with natural attrition from Alphagan 0.2% to Alphagan P 0.15%

B. Exclusions from the NMOP Formulary

1. Bosentan (Tracleer; Actelion) - excluded from the NMOP due to closed distribution system initiated by the manufacturer.
2. Lovastatin/niacin (Advicor; KOS) sustained release tablets – lovastatin is currently excluded as a formulary agent due to existing statin contract (simvastatin) that is in effect through Feb 02.

C. Clarifications to the NMOP Formulary - None

3. Quantity Limit Changes (NMOP and retail network)

A. Quantity limit for frovatriptan tablets: 9 tablets per 30 days; 27 tablets per 90 days; consistent with existing quantity limits for other triptans.

B. Quantity limit for anakinra injection (Kineret; Amgen): NMOP: 6 packs of 7 syringes per 6 weeks; Retail: 4 packs of 7 syringes per 4 weeks.

C. Quantity limit for dexmethylphenidate tablets: Standard NMOP rule for Schedule II controlled products for treatment of ADHD applies – up to 90 days supply, no refills

4. Changes to the Prior Authorization Program (NMOP and Retail Network)

A. Etanercept (Enbrel) -The FDA recently approved psoriatic arthritis as a new indication for etanercept (Enbrel). The Committee voted to add this indication to etanercept's PA criteria.

B. COX-2 Inhibitors - The Committee voted to have the same PA criteria apply to all COX-2 Inhibitors.

C. Anakinra (Kineret) - The Committee voted to adopt the Merck Medco criteria currently in place.

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